

Patent
Attorney's Docket No. 018176-381

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please amend the subject application as follows:

In the Specification:

Please replace the paragraph beginning at page 8, line 1, with the following rewritten paragraph:

--Test strip 1 is provided with an alignment mechanism which may have features 5 and 10 designed to mate with features 20 and 25 on optics shield 15. These are designed to issue positive alignment of the test strip to the optics. It is contemplated that other configurations meeting the intent of the invention are within the scope of this invention.--

Please replace the paragraph beginning on page 5, line 16, with the following rewritten paragraph:

--The system must also be able to accurately dock the test strip with the optics system including led, detector, lenses or light pipes. To achieve this a centerline alignment, or fixturing, system which minimizes rotation of the test strip carrier is required. The need to accurately describe the test strip performance with respect to the analyte concentration also helps accuracy.--

Please replace the paragraph beginning on page 11, line 3, with the following rewritten paragraph:

--The test strip 1 is comprised of a test pad 12 situated in a test pad holder 13. This holder mounts to strip fluid delivery system 14 and parts 5 and 10 provides a means for accurately positioning the test pad 12 with respect to the LED 50, and the detector 60 in addition to providing a means for blocking ambient light from effecting the analysis. The test pad 12 is impregnated with the appropriate chemistry to permit a colormetric analysis of the analyte being tested and may therefore provide a stable absorbent substrate.--

Please replace the paragraph beginning on page 11, line 10, with the following rewritten paragraph:

--The test strip of this invention provides a support for the test pad. The strip positively seats on the testing instrument, assuring proper alignment through center line

fixturing. It also seals the optics area from ambient light and blood contamination. Thus, it provides all of the functionality of a test strip and test strip holder of a conventional reflectance system. The test strip provides additional benefits in being removed after each test, facilitating easy access to the optics area for cleaning if required. With this combination part, the overall cost of the system is further reduced. When inserted into the detection device 151, the test strip 1 contacts complete a circuit which turns the device on. The device is turned off upon removal of the test strip. This eliminates a need for a separate on/off circuit or for patient action to turn the testing instrument on or off.--

Please replace the paragraph beginning at page 13, line 9, with the following rewritten paragraph:

--FIG. 5A is a block diagram showing the processing operation of the invention. Testing instrument 151 comprises a microprocessor 80 which controls the operation of the testing instrument 151. The testing instrument 151 is activated by a switching mechanism which may comprise a mechanical ON button 155 and contacts 160 - 165 which close an appropriate circuit when the button 155 is depressed. Closing of this circuit triggers operation of the device by notifying the microprocessor 80 that a measurement reading of a positioned test strip 1 is to be performed. The test strip may be one of a number of test strips in the set, and a counter keeps track of these. Alternatively, the circuit may be closed via a fluid connection using the test sample, with the contacts 170 and 175 operating as probes provided for making contact with the test pad 12 of the test strip 1 illustrated in

Fig. 5B to thereby activate the testing instrument 151 upon detection of the sample on the appropriately positioned test strip 1.--

Please replace the paragraph beginning at page 13, line 23, with the following rewritten paragraph:

--Following activation, measurement of the reaction of the sample with the reagent on the test strip 1 is effected using the detector 60. The microprocessor 80 derives an electrical signal from the electro-optical devices the LED 50, and the detector 60, and processes it to generate a detection signal indicative of analyte concentration in the tested sample. An ASIC 185 (application-specific integrated circuit) and a memory, such as RAM (random access memory) 195 or a ROM (read only memory) may be used in conjunction with the microprocessor 80, while the results of the measurement may then be displayed using LCD display 200. The results may alternatively be stored in RAM 195 for subsequent viewing or processing. The subsequent processing may be performed using the measuring instrument 151 itself, or using other devices to which the measurement results can be downloaded. One possibility in accordance with the invention is a modem link with a remote processing unit, using, e.g., telephone lines. The information may also be downloaded for storage at an internet location or electronic bulletin board for subsequent retrieval and processing or review by medical professionals. See application Serial No. 09/190,301 filed November 13, 1998, incorporated herein by reference in its entirety.--

Please replace the paragraph beginning at page 15, line 1, with the following rewritten paragraph:

--The color formed after applying the bodily fluid to the reagent test pad is proportional to the amount of analyte in the applied sample 250. The testing instrument 151, via sensor 60, ASIC 185 and microprocessor 80, measures the change in reflectance due to the development of the specific color generated by the reagent on the test strip 1. This is either used as the input to a function which relates reflectance to analyte level or to a table which correlates reflectance value to analyte level. The function or the table must be stored within the system for it to produce and display, on display 200, a reading of the analyte level in the sample 250. While most meters in use today employ functions to convert reflectance readings to analyte concentration, this approach requires that the function be stable and well understood. The use of a look up table permits the storage of specific values for reflectance and their corresponding analyte levels. The testing instrument uses this table and interpolates between the table values to give relatively accurate readings. This is achievable in a system such as that described by this invention as the table can quickly be generated for each reagent lot produced.--

Please replace the paragraph beginning at page 15, line 27, with the following rewritten paragraph:

--In the preferred embodiment, calibration is based on the response produced by a specific lot of test strips. In this manner, there is no need to presort and test the LED 50,

significantly reducing the cost of the sensor 60. The LED 50 and photodetector 60 formed from raw die elements and are placed by automated placement equipment with respect to predetermined targets on the printed circuit board. In addition, this calibration step during manufacture allows the device to compensate for a wide area of variables normally found in reflectance systems. The specific calibration data for the test strips 1 shipped with the testing instrument can be stored in the unit's read only memory (not shown). Alternatively, a master strip can be provided for setting the calibration information for that lot of strips and the master strip can be distributed therewith. A counter may be provided to limit the testing instrument 151 to performing only a specific number of tests which correlates to the quantity of test strips 1 shipped with the device. Other limitations can be built-in, such as expiration date information pertaining to the specific lot of test strips 1, with this information being contained in the measuring instrument's ROM or in the calibration chip 90 or in the master strip.--

In the Claims:

Cancel Claims 1-7 without prejudice or disclaimer of the subject matter contained therein.

Add new Claims 8-13 as follows:

8. (New) A multi-use assay system for use with a removable test strip having a test pad, the multi-use assay system comprising:
 - an electronics printed circuit board having an alignment fixturing;
 - an optics system for alignment with the removable test strip, the optics system comprising a lens, an emitter and a detector, wherein the emitter and detector are mounted in the electronics printed circuit board relative to the alignment fixturing;
 - a housing for containing the optics system and holding the removable test strip in position relative to the optics system;
 - an optics block holder mounted in the electronics printed circuit board in alignment with the alignment fixturing, the optics block holder aligning the test strip to the test pad and positioning the optics system to focus light from the light emitter and to the detector;
 - and
 - a processor in communication with the detector, the processor controlling the assay system in accordance with calibration information uniquely specific to a reagent associated with a set of one or more test strips.

9. (New) The system of Claim 8, further comprising a removable calibration chip, the calibration information being provided by the removable calibration chip.
10. (New) A multi-use assay system for use with a removable test strip having a test pad, the multi-use assay system comprising:
 - an electronics printed circuit board having an alignment fixturing;
 - an optics system for alignment with the removable test strip, the optics system comprising a lens, an emitter and a detector, wherein the emitter and detector are mounted in the electronics printed circuit board relative to the alignment fixturing;
 - a housing for containing the optics system and holding the removable test strip in position relative to the optics system;
 - an optics block holder mounted in the electronics printed circuit board in alignment with the alignment fixturing, the optics block holder aligning the test strip to the test pad and positioning the optics system to focus light from the light emitter and to the detector;
 - and
 - a processor in communication with the light detector, the processor controlling the assay system such that a predetermined number of test strips are assayed based on signals from the light detector, wherein the predetermined number corresponds to the number of test strips of a set of one or more test strips.

11. (New) The system of Claim 10, further comprising a removable calibration chip, the predetermined number being provided by the removable calibration chip.

12. (New) A multi-use assay system for use with a removable test strip having a test pad, the multi-use assay system comprising:

an electronics printed circuit board having an alignment fixturing;

an optics system for alignment with the removable test strip, the optics system comprising a lens, an emitter and a detector, wherein the emitter and detector are mounted in the electronics printed circuit board relative to the alignment fixturing;

a housing for containing the optics system and holding the removable test strip in position relative to the optics system;

an optics block holder mounted in the electronics printed circuit board in alignment with the alignment fixturing, the optics block holder aligning the test strip to the test pad and positioning the optics system to focus light from the light emitter and to the detector; and

a processor in communication with the light detector, the processor controlling the assay system such that test strips are assayed up to a predetermined expiration date.

13. (New) The system of Claim 12, wherein the predetermined expiration date corresponds to a set of one or more test strips.

REMARKS

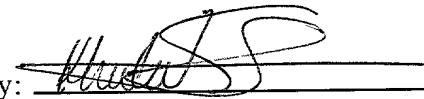
The specification has been amended to correct minor errors and better describe the invention. No new matter has been introduced.

Applicants respectfully urge that the claims of the present application define patentable subject matter and should be passed to allowance. Such allowance is respectfully solicited.

If the Examiner believes that a telephone call would help advance prosecution of the present invention, the Examiner is kindly invited to call the undersigned attorney, mR. Khaled Shami, at (650) 622-2332.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 
Khaled Shami
Registration No. 38,745

Post Office Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300

Date: April 9, 2001

Attachment to Preliminary Amendment

Marked-up Copy

Page 8, Paragraph beginning at Line 1

Test strip 1 is provided with an alignment mechanism which may have features 5 and 10 designed to mate [wit] with features 20 and 25 on optics shield 15. These are designed to issue positive alignment of the test strip to the optics. It is contemplated that other configurations meeting the intent of the invention are within the scope of this invention.

Page 5, Paragraph beginning at Line 16

The system must also be able to accurately dock the test strip with the optics system including led, detector, lenses or light pipes. To achieve this a centerline alignment, or fixturing, system which minimizes rotation of the test strip carrier is required. The need to accurately describe the test strip performance with respect to the analyte concentration also helps accuracy.

Page 11, Paragraph beginning at Line 3

The test strip 1 is comprised of a test pad 12 situated in a test pad holder 13. This holder mounts to strip fluid delivery system 14 and [parts 13 and 14] parts 5 and 10 provides a means for accurately positioning the test pad 12 with respect to the LED 50, and the

detector 60 in addition to providing a means for blocking ambient light from effecting the analysis. The test pad 12 is impregnated with the appropriate chemistry to permit a colormetric analysis of the analyte being tested and may therefore provide a stable absorbent substrate.

Page 11, Paragraph beginning at Line 10

The test strip of this invention provides a support for the test pad. The strip positively seats on the testing instrument, assuring proper alignment through center line fixturing. It also seals the optics area from ambient light and blood contamination. Thus, it provides all of the functionality of a test strip and test strip holder of a conventional reflectance system. The test strip provides additional benefits in being removed after each test, facilitating easy access to the optics area for cleaning if required. With this combination part, the overall cost of the system is further reduced. When inserted into the detection device [180] 151, the test strip 1 contacts complete a circuit which turns the device on. The device is turned off upon removal of the test strip. This eliminates a need for a separate on/off circuit or for patient action to turn the testing instrument on or off.

Page 13, Paragraph beginning at Line 9

FIG. 5A is a block diagram showing the processing operation of the invention. Testing instrument 151 comprises a microprocessor 80 which controls the operation of the testing instrument 151. The testing instrument 151 is activated by a switching mechanism which

may comprise a mechanical ON button 155 and contacts 160 - 165 which close an appropriate circuit when the button [55] 155 is depressed. Closing of this circuit triggers operation of the device by notifying the microprocessor [151] 80 that a measurement reading of a positioned test strip 1 is to be performed. The test strip may be one of a number of test strips in the set, and a counter keeps track of these. Alternatively, the circuit may be closed via a fluid connection using the test sample, with the contacts 170 and 175 operating as probes provided for making contact with the test pad 12 of the test strip 1 illustrated in Fig. 5B to thereby activate the testing instrument 151 upon detection of the sample on the appropriately positioned test strip 1.

Page 13, Paragraph beginning at Line 23

Following activation, measurement of the reaction of the sample with the reagent on the test strip 1 is effected using the detector 60. The microprocessor 80 derives an electrical signal from the electro-optical devices the LED 50, and the detector 60, and processes it to generate a detection signal indicative of analyte concentration in the tested sample. An ASIC [190] 185 (application-specific integrated circuit) and a memory, such as RAM (random access memory) 195 or a ROM (read only memory) may be used in conjunction with the microprocessor 80, while the results of the measurement may then be displayed using LCD display 200. The results may alternatively be stored in RAM 195 for subsequent viewing or processing. The subsequent processing may be performed using the measuring instrument [80] 151 itself, or using other devices to which the measurement

results can be downloaded. One possibility in accordance with the invention is a modem link with a remote processing unit, using, e.g., telephone lines. The information may also be downloaded for storage at an internet location or electronic bulletin board for subsequent retrieval and processing or review by medical professionals. See application Serial No. 09/190,301 filed November 13, 1998, incorporated herein by reference in its entirety.

Page 15, Paragraph beginning at Line 1

The color formed after applying the bodily fluid to the reagent test pad is proportional to the amount of analyte in the applied sample 250. The testing instrument 151, via sensor 60, ASIC [190] 185 and microprocessor 80, measures the change in reflectance due to the development of the specific color generated by the reagent on the test strip 1. This is either used as the input to a function which relates reflectance to analyte level or to a table which correlates reflectance value to analyte level. The function or the table must be stored within the system for it to produce and display, on display 200, a reading of the analyte level in the sample [16] 250. While most meters in use today employ functions to convert reflectance readings to analyte concentration, this approach requires that the function be stable and well understood. The use of a look up table permits the storage of specific values for reflectance and their corresponding analyte levels. The testing instrument uses this table and interpolates between the table values to give relatively accurate readings. This is achievable in a system such as that described by this invention as the table can quickly be generated for each reagent lot produced.

Page 15, Paragraph beginning at Line 27

In the preferred embodiment, calibration is based on the response produced by a specific lot of test strips. In this manner, there is no need to presort and test the LED 50, significantly reducing the cost of the sensor 60. The LED 50 and photodetector 60 formed from raw die elements and are placed by automated placement equipment with respect to predetermined targets on the printed circuit board. In addition, this calibration step during manufacture allows the device to compensate for a wide area of variables normally found in reflectance systems. The specific calibration data for the test strips 1 shipped with the testing instrument can be stored in the unit's read only memory (not shown). Alternatively, a master strip can be provided for setting the calibration information for that lot of strips and the master strip can be distributed therewith. A counter may be provided to limit the testing instrument [80] 151 to performing only a specific number of tests which correlates to the quantity of test strips 1 shipped with the device. Other limitations can be built-in, such as expiration date information pertaining to the specific lot of test strips 1, with this information being contained in the measuring instrument's ROM or in the calibration chip 90 or in the master strip.